UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *ex rel.* JAMES F. ALLEN, Plaintiff, v. ALERE HOME MONITORING, INC.; ROCHE HEALTH SOLUTIONS, INC.; ADVANCED CARDIO SERVICES; CARDIOLINK CORP.; MDINR, LLC; PATIENT HOME MONITORING, INC.; TAMBRA INVESTMENTS, INC. d/b/a REAL TIME DIAGNOSTICS; and US HEALTHCARE SUPPLY, LLC, Defendants.	FILED UNDER SEAL AS REQUIRED BY 31 U.S.C. § 3730(b) (VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT) Civil Action No. 16-cv-11372-ADB **DEMAND FOR JURY TRIAL**

FIRST AMENDED COMPLAINT

Plaintiff-Relator James F. Allen ("Allen" and/or the "Relator"), by and through his attorneys, SMITH & BRINK, P.C., and on behalf of the United States of America, hereby alleges as follows against defendants Alere Home Monitoring, Inc. ("Alere"), Roche Health Solutions, Inc. ("Roche"), Advanced Cardio Services ("ACS"), Cardiolink Corp. ("Cardiolink"), mdINR, LLC ("mdINR"), Patient Home Monitoring, Inc. ("PHM"), Tambra Investments, Inc. d/b/a Real Time Diagnostics ("RTD"), and US Healthcare Supply, LLC ("US Healthcare") (collectively, the "defendants").

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and fraudulent records, statements, and claims made, caused to be made, used, caused to be used, presented, and caused to be presented by the defendants and

their agents, employees, representatives, and co-conspirators in violation of the federal False Claims Act, 31 U.S.C. § 3729, *et seq*., as amended (the "FCA" and/or the "Act").

2. The defendants are independent diagnostic testing facilities ("IDTFs") that provide portable monitors and supplies to patients on long-term warfarin therapy so the patients can test their prothrombin time ("PT"), measured using the international normalized ratio ("INR"), at home.

3. As described herein, each defendant has intentionally developed mandatory testing frequency minimums and marketing practices that directly and knowingly lead to medically unnecessary PT/INR testing, the bills for which are submitted to Medicare for reimbursement.

4. Specifically, each defendant instituted a policy that requires patients to test their INR at least bi-weekly (Alere, Roche, and US Healthcare) or weekly (ACS, Cardiolink, mdINR, PHM, and RTD).

5. This required testing frequency was mandated not because of medical necessity, but rather because the Centers for Medicare & Medicaid Services' ("CMS") National Coverage Determination ("NCD") for home INR testing allows reimbursement for home PT/INR testing performed weekly, if necessary.

6. Defendant Alere also submitted charges to CMS for INR testing services that were not actually rendered.

7. In 2015, the most recent year for which data identifying charges submitted by individual providers is available, the defendants collectively received $116,291,834.80 in payments from CMS for home PT/INR testing. This amounted to 90.5% of the total paid by CMS for home INR testing in 2015. *See* Exhibit 1.

8. For context, in 2008, which was the first year that CMS issued the current NCD for home INR testing (on March 19), a total of $5,548,306.95 was paid by CMS for home INR testing to all providers. Id.

9. The defendant IDTFs achieved this twenty-fold increase in revenue in just seven (7) years by substituting their own mandated testing frequency for the independent medical judgment of physicians, and by pressuring doctors and patients to utilize unnecessary PT/INR testing in order to maximize CMS reimbursement for every patient in their programs.

10. As each defendant knows, Medicare only covers tests that are reasonable and necessary for the treatment or diagnosis of an individual patient's illness or injury. 42 U.S.C. § 1395y(a)(1)(A). The need for each test must be individually assessed and documented in the patient's medical chart. 42 U.S.C. §§ 410.32(a), (d)(2).

11. The United States government reasonably relied on each defendant's bills to contain truthful and accurate representations regarding the reasonableness and necessity of the home INR testing provided.

12. As detailed below, the Relator has developed significant personal and exclusive knowledge confirming the defendants' fraud that has cost the United States government millions of dollars in false claims.

II. THE PARTIES

A. PLAINTIFF

13. The real party in interest to the claims of this action is the United States of America.

14. Plaintiff-Relator James F. Allen is a citizen and resident of the State of New York.

15. Allen brings this action on behalf of the federal government pursuant to 31 U.S.C. § 3730(b).

B. DEFENDANTS

16. Alere Home Monitoring, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 51 Sawyer Road, Suite 200, Waltham, Massachusetts, 02453.

17. Roche Health Solutions, Inc. is a corporation organized and existing under the laws of the State of Minnesota with a principal place of business at 9115 Hague Road, Indianapolis, Indiana, 46250.

18. Advanced Cardio Services is a corporation organized and existing under the laws of the State of California with a principal place of business at 2544 Campbell Place, Suite 275, Carlsbad, California, 92009.

19. Cardiolink Corp. is a corporation organized and existing under the laws of the State of New York with a principal place of business at 1 North Village Green, Levittown, New York, 11756.

20. mdINR, LLC is a limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at 59 Windsor Highway, Suite 240, New Windsor, New York, 12553.

21. Patient Home Monitoring, Inc. is a corporation organized and existing under the laws of the State of Washington with a principal place of business at 14724 Ventura Boulevard, Suite 1250, Sherman Oaks, California, 91403.

22. Tambra Investments, Inc. d/b/a Real Time Diagnostics is a corporation organized and existing under the laws of the State of Michigan with a principal place of business at 17610 Fairway Drive, Detroit, Michigan, 48221.

23. US Healthcare Supply, LLC is a limited liability company organized and existing under the laws of the State of New Jersey, with a principal place of business at 304 Waterford Terrace, Easton, Pennsylvania, 18042.

III. JURISDICTION AND VENUE

24. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

25. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a), which provides for nationwide service of process as the defendants each have sufficient minimum contacts with the United States of America.

26. Additionally, the defendants can be found in, reside in, transact, or have transacted business within the District of Massachusetts.

27. Venue is proper in the District of Massachusetts pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

IV. SOURCE OF RELATOR'S ALLEGATIONS

28. Allen is unaware of any public disclosure of the information or allegations that form the basis of this Complaint.

29. The facts and circumstances alleged in this Complaint regarding the defendants' billing for services not rendered and their exploitative business practices which cause the performance of unnecessary and excessive home INR testing, the bills for which are then

submitted to CMS for reimbursement, have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, government account office report, hearing, audit investigation, or in the news media.

30. Allen has direct, personal, and exclusive knowledge of the information upon which the factual allegations contained in this Complaint are based, namely, the defendants' billing for services not rendered and exploitative business practices which cause unnecessary and excessive home INR testing to be performed and billed to CMS.

31. Prior to the filing of this action, Allen voluntarily provided information to the United States government regarding the false claims that are the subject of this Complaint.

32. Allen is a 70-year-old former Marine who served in Vietnam between 1966 and 1968. Mr. Allen received three (3) Purple Hearts as a result of his service, and was honorably discharged in 1968.

33. Allen has been on warfarin therapy since March 3, 2010 to treat atrial fibrillation and depressed left ventricle function.

34. Allen initially underwent INR testing at a Department of Veterans Affairs ("VA") facility near his home in Buffalo, New York. After his INR stabilized, Allen tested his INR at the VA approximately once per month.

35. In early 2013, Allen transferred the management of his warfarin treatment and INR testing to his cardiologist, Dr. Brian J. Riegel, M.D. ("Dr. Riegel"), at Buffalo Cardiology & Pulmonary Associates ("BCPA") in Buffalo, New York.

36. INR monitoring at BCPA is conducted through its Coumadin Clinic. The BCPA Coumadin Clinic uses an algorithm to determine the frequency with which patients should test their INR ("BCPA algorithm"). *See* Affidavit of Dr. Riegel, annexed hereto at Exhibit 2, ¶¶ 5-6.

37. The BCPA algorithm was developed by a committee of BCPA cardiologists and Coumadin Clinic managers, based on review and analysis of the most recent and relevant medical research regarding frequency of INR testing. Id. at ¶ 6.

38. The BCPA algorithm calls for INR testing to be performed at different intervals based on the result of the previous test. For example, if an INR test result is slightly outside of the target range, the algorithm directs that a small warfarin dose adjustment be made and a repeat test be performed sooner than would be normal. If a test result is far outside of the target range, the cardiologist is notified and an independent decision regarding dose adjustment and interval before INR re-test is made. If a patient has reported two (2) consecutive in-range test results, the BCPA algorithm directs that INR testing be performed once every four (4) weeks. Id.; Exhibit 3 (setting out the BCPA algorithm).

39. In 2014, Allen moved to Canandaigua, New York, which is nearly 100 miles from the BCPA clinic. Because of the significant distance and travel time between his new home and the clinic to have his INR tested, Allen decided to enroll in a home INR testing program. *See* Affidavit of Allen annexed hereto at Exhibit 4 (hereinafter "Allen Affidavit"), ¶ 7.

40. Dr. Riegel signed a Roche "Physician Order for PT/INR Patient Self-Testing" for Allen on May 8, 2013. *See* Exhibit 2, ¶ 12.

41. Allen performed his first INR test at home using Roche's system on March 2, 2014. *See* Allen Affidavit, ¶ 9.

42. Because he was using a new testing system, Allen tested his INR on March 13, 2014 and April 3, 2014, at which point he had had five (5) consecutive in-range INR readings. Id.

43. When Allen called in his INR result to the BCPA Coumadin Clinic on April 3, 2014, he was instructed to perform his next INR test on May 1, 2014. This was in accordance and consistent with all of his previous experience taking INR tests and his understanding of Dr. Riegel's instructions and the BCPA algorithm. Id. at ¶ 10.

44. On April 28, 2014, Roche mailed Allen a letter stating that he had missed an INR test scheduled for the week of April 14, 2014. Id. at ¶ 11.

45. This letter led to a series of discussions with Roche and clarifications about the medically necessary INR test frequency for Allen made by his physicians at BCPA, detailed *infra* and in the annexed Allen Affidavit, which culminated in Roche kicking Allen out of its home testing program because Allen refused to consent to performing unnecessary tests.

46. Allen then communicated with representatives of each defendant and attempted to enroll in their home INR testing programs using the test intervals that Dr. Riegel prescribed.

47. During the course of this process, Allen discovered that each defendant uses mandated testing frequencies, misleading marketing materials, and improper coercion to remove physicians from their roles as the assessors of the reasonable and necessary frequency of home INR testing and forces patients to instead test at the minimum intervals mandated by the defendant IDTFs, usually at the maximum rate that CMS will reimburse, resulting in substantial bills submitted for unreasonable and unnecessary home INR testing.

V. SUMMARY OF RELEVANT FEDERAL LAW AND PROGRAMS

A. FEDERAL CIVIL FALSE CLAIMS ACT

48. The FCA was originally enacted in 1863 and was substantially amended in 1986 by the False Claims Amendments Act. Congress enacted the 1986 amendments to enhance and modernize the federal government's tools for recovering losses sustained by frauds against it

after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of government frauds to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to assisting the government in prosecuting government contractor fraud.

49. The Act provides that any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval to the United States government or knowingly makes, uses, or causes to be made or used false records and statements to induce the United States to pay or approve false and fraudulent claims, is liable for a civil penalty of up to $10,000 for each such claim plus three (3) times the amount of damages which the government sustains because of the act of that person. 31 U.S.C. § 3729(a)(1).

50. "[T]he terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud." 31 U.S.C. §§ 3729(b)(1).

51. The Act permits any person having information about false or fraudulent claims to bring an action for himself and the government and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time). Based on these provisions, *qui tam* Relator James F. Allen, on behalf of the United States government, seeks through this action to recover treble damages and civil penalties arising from the false and fraudulent actions described herein. 31 U.S.C. § 3730.

B. THE SOCIAL SECURITY ACT AND MEDICARE

52. The Medicare program is codified at Title XVIII of the Social Security Act. 42 U.S.C. § 1395. Medicare benefits are available for persons who are qualified on the basis of age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1.

53. CMS administers the Medicare program. CMS contracts with private companies called Medicare Administrative Contractors ("MACs"), to review and pay claims submitted by health care providers. 42 U.S.C. § 1395kk-1.

54. The Medicare program has four (4) parts. All bills submitted by the defendants at issue herein were submitted under Part B, which covers clinical laboratory test services. 42 U.S.C. § 1395k.

55. All providers, including IDTFs, must certify compliance with the Medicare statute and its regulations before participation in the program. 42 C.F.R. § 424.516(a)(1).

56. Certification is accomplished through the submission of CMS Form-855B, which must be signed by an authorized official of any entity seeking to participate in the Medicare program, and which "commit[s] the organization to fully abide by the statutes, regulations, and program instructions of the Medicare program."

57. Authorized officials of each defendant signed the certification statement in Section 15 of Form CS-955B, indicating that they understood that the IDTF was required to comply with Medicare laws, regulations, and program instructions.

58. Medicare only covers medical expenses that are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. 42 U.S.C. § 1395y.

59. Clinical laboratory testing is covered under Medicare pursuant to 42 U.S.C. § 1395x(s)(3).

60. Laboratory testing services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" are excluded from coverage under Medicare. 42 U.S.C. § 1395y(a)(1)(A).

61. All diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32(a).

62. In other words, laboratory tests that are not individualized to patient need are not covered by Medicare.

63. The Medicare Benefit Policy Manual defines a physician "order" as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary," the need for which must be clearly documented in the patient's medical record. Ch. 15, §80.6.1.

64. "Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32(a).

65. IDTFs are required to maintain documentation, and to produce the same to CMS if requested, that establishes that all testing performed is reasonable and necessary. 42 C.F.R. § 410.32(d)(3).

66. The CMS regulations specifically empower IDTFs to ensure the reasonableness and necessity of tests performed by allowing them to request "additional diagnostic and other

medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary." 42 C.F.R. § 410.21(d)(3)(C)(iii).

67. The Department of Health and Human Services, Office of Inspector General ("OIG") was established to fight waste, fraud, and abuse in the Medicare program. It has published guidelines that state, *inter alia*: "[IDTFs] should construct the [diagnostic test] requisition form to ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill." 63 Fed. Reg. 45079 (Aug. 24, 1998).

68. The OIG also notes that "too often [standing orders] have led to abusive practices. Standing orders in and of themselves are not usually acceptable documentation that tests are reasonable and necessary." Id. at 45081.

C. OTHER FEDERAL HEALTH CARE PROGRAMS

69. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE") provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired, and deceased members. The program is administered by the Department of Defense and funded by the federal government. 10 U.S.C. §§ 1071-1110.

70. TRICARE covers only "medically necessary services and supplies required in the diagnosis and treatment of illness or injury." 32 C.F.R. 199.4(a)(1)(i).

71. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. 5 U.S.C. § 8901, *et seq*.

72. The Office of Personnel Management implements coverage by entering into contracts with insurance carriers through which the federal government pays approximately 75% of plan premiums. 5 U.S.C. § 8906(b).

VI. DEFENDANTS' FRAUDULENT SCHEMES

A. BACKGROUND ON WARFARIN AND PT/INR TESTING

73. Warfarin is a vitamin K antagonist that inhibits blood clotting factors II, VII, IX, and X. It is prescribed to patients with certain cardiac conditions to reduce the incidence of thromboembolic events. Warfarin is normally prescribed as a lifetime-long treatment.

74. The goal of warfarin treatment is to maintain patients' INR within a therapeutic range determined by the patient's physician. The effectiveness of warfarin therapy is commonly measured by time in therapeutic range ("TTR").

75. When an INR is below the therapeutic range, the risk of thromboembolic events is increased. When an INR is above the therapeutic range, the risk of uncontrolled bleeding events is increased.

76. The therapeutic range is narrow and varies based on the cardiac condition that necessitates the therapy.

77. Because of the narrow therapeutic range of INR, the risk of unexpected fluctuation in INR, and the potentially fatal risks of out-of-range INR, patients on warfarin therapy must regularly undergo blood testing so that their physicians can adjust the warfarin dose if needed.

78. The anticoagulant effect of warfarin can differ substantially between patients, and a patient's INR level must be monitored frequently at the outset of treatment so that the

physician can find the correct dose. Once the physician determines the correct warfarin dose, and the patient's INR results are stable, the needed frequency of INR testing is reduced.

79. The primary source of guidance for physicians prescribing warfarin and INR testing is the American College of Chest Physicians ("ACCP"). The ACCP defines a stable INR as one that has maintained consistent results over the course of at least three (3) months without the need for warfarin dose adjustment. Anne Holbrook et al., *Evidence-Based Management of Anticoagulant Therapy*, 141 CHEST e152S-e184S, e160S (2012).

80. Historically, stable patients in North America have their INR tested once every four (4) weeks. Id.

81. The current ACCP guidelines recommend that warfarin patients with stable INR test at a frequency of up to once every twelve (12) weeks. Id.

82. Testing once monthly is by far the most common interval ordered by physicians in the United States, and is the generally accepted standard practice.

83. A monthly interval between INR tests for patients who are stable offers a cost-effective means of ensuring safe anticoagulation levels.

84. The Food and Drug Administration ("FDA") approved warfarin for use as an anticoagulant in 1954.

85. From 1954 through the 1980s, INR testing was exclusively performed by venous blood draws at medical clinics.

86. In the late 1980s, companies began to develop and market portable machines that permitted INR testing to be performed by patients in their own homes.

87. This new home INR testing was routinely denied for coverage by regional Medicare contractors until July 1, 2002, when CMS issued NCD 190.11. NCD 190.11 directed

contractors to reimburse claims for home INR testing for patients with mechanical heart valves on warfarin therapy when certain conditions were met.

88. On October 4, 2006, the FDA added a "black box warning" to warfarin that reads, *inter alia*, "[r]egular monitoring of INR should be performed on all treated patients."

89. After the time FDA added this black box warning to warfarin, a group of companies that sold home INR testing monitors and supplies, including Roche and a predecessor to Alere, formed the Prothrombin-Time Self Testing Coalition to lobby CMS to expand its coverage of home INR testing to include all patients on warfarin therapy (not just those with mechanical heart valves).

90. In 2007, the Prothrombin-Time Self Testing Coalition filed a formal written request to CMS asking for reconsideration of NCD 190.11.

91. On March 19, 2008, CMS issued an updated version of NCD 190.11 that expanded reimbursement of expenses related to home INR testing to patients requiring warfarin therapy because of atrial fibrillation and venous thromboembolism, in addition to those with mechanical heart valves.

92. NCD 190.11 requires that the monitor and home testing be prescribed by a treating physician as provided at 42 CFR § 410.32(a).

93. NCD 190.11 also imposes the following requirements:

a. The patient must have been anticoagulated for at least 3 months prior to the use of the home INR device; and

b. The patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated the correct use of the device prior to its use in the home; and

c. The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring; and

d. Self-testing with the device should not occur more frequently than once a week.

94. At the same time that the updated NCD 190.11 was issued, CMS also updated its Medicare Claims Processing Manual. The instructions for billing expenses for home INR testing are found at Chapter 32, Section 60.4.2.

95. The CMS Claims Processing Manual directs that expenses related to home INR testing be billed using three separate Healthcare Common Procedure Coding System (HCPCS) codes: G0248, G0249, and G0250.

96. HCPCS code G0248 is the code used for the required initial face-to-face demonstration on the use of the home INR monitor.

97. HCPCS code G0249 is the code used by IDTFs for provision of test materials and equipment, and reporting results to physicians. This code can only be billed once every four (4) tests that the patient takes.

98. HCPCS code G0250 is the code used by physicians for review and interpretation of the results of the home INR testing.

99. The Program Memorandum establishing the home INR testing payment procedure (Transmittal AB-02-064, May 2, 2002) further provides that "this is a CLIA waived diagnostic test and it is not covered as durable medical equipment . . . [a]lso note that the cost of the device and supplies are included in the payment for G0249 and therefore not separately billed to Medicare."

100. Transmittal AB-02-064 reiterates that "the monitor and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32(a)."

B. THE DEFENDANTS TARGETED MEDICARE

101. Each defendant knowingly submitted and caused to be submitted false claims to CMS for home INR testing that was not reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 410.32(a).

102. There are an estimated 2,200,000 people in the United States with atrial fibrillation. The median age of patients with atrial fibrillation is 75 years, and 70% of patients are between 65 and 85 years of age. William M. Feinberg et al., *Prevalence, Age Distribution, and Gender of Patients With Atrial Fibrillation*, 155(5) ARCH INTERN MED. 469-473 (1995). There are an estimated 400,000 people in the United States with mechanical heart valves. As with atrial fibrillation, the incidence is very low in younger patients, only 0.2 per 1,000 in ages 44 and under, increasing to 5.3 per 1,000 in patients 75 and older. Martijn W.A. van Geldorp et al., *Patient Outcome After Aortic Valve Replacement with a Mechanical or Biological Prosthesis: Weighing Lifetime Anticoagulant-Related Event Risk Against Reoperation Risk*, 137(4) JOURNAL OF THORACIC AND CARDIOVASCULAR SURGERY 881-886 (2009).

103. As Medicare eligibility begins at age 65 (or earlier, if based upon disability), the patient population targeted by the defendants consists primarily of Medicare beneficiaries.

104. Each defendant is aware that the vast majority of its targeted patient population is covered by Medicare.

105. Each defendant trains its sales representatives to assure physicians and patients that Medicare will cover the tests performed.

106. Each defendant trains its sales representatives to inform physicians and patients that Medicare will not question the necessity of tests performed so long as they are not performed more than once per week.

107. The enrollment forms used by Alere, Roche, and RTD explicitly state that Medicare allows testing to be performed weekly. The enrollment form used by ACS falsely claims that Medicare recommends weekly testing. None of the defendants use enrollment forms that refer to the payment policies of any other payor but Medicare. *See* Allen Affidavit, Exhibits F (Roche 2013 enrollment form), H (Roche 2014 enrollment form), Q (Alere 2013 enrollment form), U (former versions of Alere enrollment form), JJ (undated ACS enrollment form), and TT (undated mdINR enrollment form); Exhibit 5 annexed hereto (undated PHM enrollment form); Exhibit 6 annexed hereto (undated Cardiolink enrollment form); Exhibit 7 annexed hereto (undated RTD enrollment form); Exhibit 8 annexed hereto (2015 and 2016 Roche enrollment forms); and Exhibit 9 annexed hereto (2011-2016 versions of mdINR enrollment form).

108. Each defendant that Allen contacted after being discharged by Roche represented to him that Medicare would cover his testing performed weekly or bi-weekly, even though Allen informed each such defendant that his doctor believed that it was only medically necessary to test his INR monthly.

109. Thus, each defendant engaged in a calculated scheme to pressure patients on warfarin therapy to undergo excessive INR testing that was medically unnecessary, and to convince their physicians to prescribe the same, specifically to target Medicare reimbursement.

110. This scheme bore no relation to the clinical and medical needs of patients, but rather was devised and implemented for the sole purpose of generating revenue for the defendants.

C. THE DEFENDANTS KNOWINGLY CAUSED MEDICALLY UNNECESSARY INR TESTS TO BE PERFORMED

1. Enrollment Criteria and Testing Frequency

111. Each defendant knowingly developed enrollment criteria for its home INR testing program that were designed to maximize the amount of reimbursement each defendant could obtain from CMS, without regard to the actual medical reasonableness or necessity of the tests that were performed.

112. Four (4) of the defendants – mdINR, PHM, ACS, and RTD – require all patients to test their INR weekly, which maximizes the reimbursement they can seek from CMS (as discussed above, CMS will reimburse IDTFs for a maximum of four (4) tests per month).

113. Two (2) of the defendants – Alere and Roche – require patients to test bi-weekly.

114. US Healthcare requires patients to test weekly or bi-weekly until it has recouped the cost of the testing meter from CMS. Thereafter, US Healthcare has stated that it will adhere to the opinion of the prescribing physician and allow for less frequent testing.

115. Cardiolink allows patients to test at the frequency prescribed by a physician, but has represented that it will nevertheless bill Medicare for weekly testing.

116. None of the defendants allows patients to test at the interval their physician believes to be medically necessary, if the physician believes that testing less frequently than bi-weekly is appropriate (with the exception of Cardiolink, as it bills Medicare for the maximum testing allowed regardless of tests performed).

117. Testing INR once monthly is the most common interval ordered by U.S. physicians. *See Evidence-Based Management of Anticoagulant Therapy*, 141 CHEST at e160S. The defendants' testing frequency mandate therefore excludes the most common testing interval used by cardiologists.

118. At least seven (7) of the defendants (the only defendant whose enrollment form Allen did not obtain is US Healthcare) utilize pre-printed enrollment forms that are knowingly designed to remove INR test frequency decision-making from physicians and to ensure that patients test as often as possible. *See* Allen Affidavit, Exhibits F, H, Q, U, JJ, and TT; Exhibits 5-9.

119. Each defendant that utilizes a pre-printed enrollment form requires it to be filled out and signed by a physician before a patient can begin use of its home INR testing products and service. Id.

120. The enrollment forms used by the defendants are not patient-specific, as the physician choices contained therein are limited by the options that are available to select. Id.

121. None of the present enrollment forms used by the defendants contain an option for a physician to override the testing frequency selected in any circumstances, including in response to abnormal test results. Id.

122. As discussed above, the OIG has provided official commentary regarding the type of enrollment forms utilized by the defendants: "standing orders . . . too often . . . have led to abusive practices."

123. The OIG has further stated that "[s]tanding orders in and of themselves are not usually acceptable documentation that tests are reasonable and necessary." Id.

124. The OIG has stated that "[t]he laboratory should construct the requisition form to ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill." Id.

125. The enrollment forms used by the defendants do not contain any instruction that the prescribing physician should make an independent medical judgment about the frequency of

the testing that the patient is to undergo in the program, as recommended by the Office of the Inspector General. Instead, the opposite is true: the enrollment forms remove any element of discretion and independent medical necessity from the physicians. *See* Allen Affidavit, Exhibits F, H, Q, U, JJ, and TT; Exhibits 5-9.

126. The OIG has also stated that "when claims for medically unnecessary services are discovered, Medicare holds the billing laboratory financially responsible for any incorrect payments." Office of Inspector General, OEI-05-00-00070, Medicare Payments for Clinical Laboratory Services: Vulnerabilities and Controls (2000) (emphasis added).

127. Instead of taking steps to ensure that they were only submitting claims for necessary INR testing, the defendants worked to increase the number of medically unnecessary tests they performed and, therefore, billed to CMS.

2. Marketing Practices

128. Each defendant knowingly engages in marketing practices that are intended to pressure patients to test more frequently than is medically necessary and to pressure doctors into prescribing more tests than are medically necessary.

129. To accomplish their objective of maximizing the number of tests ordered and performed, the defendants knowingly present patients and physicians with information and data that is false and/or misleading.

130. For example, five (5) of the eight (8) defendants (Alere, mdINR, Roche, PHM, and RTD) distribute marketing material that contains reference to a 2006 article called *Self-monitoring of oral anticoagulation: a systematic review and meta-analysis* to support their assertion that frequent home monitoring is superior to other methods of INR testing. Carl Heneghan et al., 367 LANCET 404-411 (2006) ("Heneghan 2006 Article"). This retrospective

analysis of fourteen (14) different studies was published two years before CMS issued the updated NCD 190.11 that permitted reimbursement for home INR monitoring for atrial fibrillation patients for the first time. The studies analyzed were conducted between 1989 and 2005, and only two (2) were conducted in the United States. The article does not contain any reference to the average frequency with which the self-monitoring patients analyzed tested their INR levels. An average would not be calculable even if a patient or physician was inclined to review all fourteen (14) underlying studies, because only nine (9) of the individual studies reported the testing frequency of the participants. Id. at 408. Of the nine (9) studies that provided information, the test frequency ranged from 29.22 to 98.54 tests per year. Id. Over 10,000 of the participants of the studies analyzed tested their INR far more frequently than the once a week maximum that CMS and the defendants allow. Id. Thirteen (13) of the studies also included patients self-adjusting their warfarin dosage, a practice that is not used in the United States. Id.

131. Reference and citation to the Heneghan 2006 Article by the defendants is knowingly intended to lead patients and physicians into believing that outcomes will be improved if tests are performed at the frequency pushed by the defendants.

132. To the extent that the method and frequency of self-monitoring in the studies analyzed by the Heneghan 2006 Article is even ascertainable, they bear no resemblance to the practices utilized in the United States and promoted by the defendants.

133. Further, a follow-up study called *Self-monitoring of oral anticoagulation: a systematic review and meta-analysis of individual patient data* was published in 2012 by the same authors of the Heneghan 2006 Article. Carl Heneghan et al., 379 LANCET 322-334 (2012) ("Heneghan 2012 Article"). In that publication, citing their own previous study, the authors

admit that "previous conclusions were limited by methodological problems and inadequate reporting of important outcome data over time." Id. at 322. The Heneghan 2012 Article found that there was no statistically significant reduction in incidence of death and hemorrhage in patients who use home monitors (again without reference to frequency of testing), and a statistically significant reduction in stroke that was solely a result of a "striking reduction" in patients under 55. In other age groups, the results were non-significant. Id. at 326.

134. Allen did not uncover a single reference to the Heneghan 2012 Article disclaiming the results of the Heneghan 2006 Article in the promotional materials of any of the defendants.

135. Nor did Allen uncover statements or promotional materials of any of the defendants that direct patient or physician attention to the more recent and more relevant articles that almost uniformly find that increasing frequency of INR monitoring does not improve patient outcomes, including the practice guidelines of the American College of Chest Physicians. *See, e.g.,* David B. Matchar et al., *Effect of Home Testing of International Normalized Ratio on Clinical Events*, 368 NEW ENG. J. MED. 1608-1620 (2010); David B. Matchar et al., *The Impact of Frequency of Patient Self-testing of Prothrombin Time on Time in Target Range within VA Cooperative Study #481: The Home INR Study (THINRS), a Randomized, Controlled Trial*, 40 J. THROMB. THROMBOLYSIS 17-25 (2015); Anne Holbrook et al., *Evidence-Based Management of Anticoagulant Therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed.: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines*, 141 CHEST e152S-e184S (2012); Adam J. Rose et al., *Reexamining the Recommended Follow-up Interval After Obtaining an In-Range International Normalized Ratio Value*, 140 CHEST 359-365 (2011); D.M Witt et al., *Twelve-month Outcomes and Predictors of Very Stable INR Control in*

Prevalent Warfarin Users, 8 J THROM HAEMOST 744-749 (2010); Sam Schulman et al., *Warfarin Dose Assessment Every 4 Weeks Versus Every 12 Weeks in Patients With Stable International Normalized Ratios: A Randomized Trial*, 155 ANN INTERN MED 655-659 (2011).

136. Knowingly presenting data that is outdated, misleading, and in at least one prominent case, disclaimed by its own authors, serves to further the defendants' efforts to persuade physicians to order, and patients to undergo, tens of thousands of INR tests that are medically unnecessary.

137. The most recent study addressing frequency of home monitoring of INR, and possibly the only prospective study in which various intervals of home INR testing were evaluated, *The Impact of Frequency of Patient Self-testing of Prothrombin Time*, found that patients who tested every week had a mean time of INR in the prescribed therapeutic range ("TTR") of 63.3%, while patients who tested every four (4) weeks had a mean TTR of 59.9%, a difference that the authors describe as "modest." 40 J. THROMB. THROMBOLYSIS at 20. The authors further noted that "[g]iven the costs of the self-testing meter and related supplies, these results raise the possibility that more frequent testing should be restricted to patients whose INR values are unstable, a strategy consistent with current ACCP recommendations." Id. at 22.

138. The ACCP currently recommends that patients who have consistently stable INR levels can test up to once every twelve (12) weeks. *Evidence-Based Management of Anticoagulant Therapy*, 141 CHEST at e160S (2012).

139. In practice, home INR monitoring is prescribed by cardiologists when patients have difficulty with transportation or, like Allen, live a great distance from the nearest testing facility.

140. The defendants have no medical basis to claim that patient outcomes are improved for patients who test weekly as a rule rather than at the direction of their physicians, including on a monthly basis if so prescribed.

141. If the defendants had not presented patients and physicians with outdated, false, and misleading marketing materials, many millions of dollars of claims for medically unnecessary tests would not have been ordered and therefore would not have been submitted to CMS for reimbursement.

D. SPECIFIC EVIDENCE REGARDING EACH DEFENDANT

1. Alere Home Monitoring, Inc.

142. Allen contacted Alere to inquire about enrollment in its home INR testing service by correspondence dated January 7, 2015. This initial letter sent by Allen disclosed that his physician was directing that his INR levels be tested once monthly while his levels are stable. *See* Allen Affidavit, ¶ 22 and Exhibit K.

143. Mary Wages ("Wages"), a representative of Alere with the title of "Area Business Manager," responded to Allen's inquiry by email on January 9, 2015. Wages informed Allen that Alere requires that he test at least twice per month. Id. at ¶ 22 and Exhibit L.

144. On January 10, 2015, Allen sent Wages an email questioning this requirement in light of the fact that he had only been testing monthly when his INR levels were stable. Id. at ¶ 24 and Exhibit M.

145. Wages replied, by email sent on January 12, 2015, that "[Alere's] program has a minimum testing frequency of 2x/month, other companies even require weekly testing." Id. at ¶ 25 and Exhibit N.

146. Wages's response evidences Alere's awareness that the entire home-testing market imposes testing frequency criteria that have no correlation to medical need.

147. On January 13, 2015, Allen again questioned Wages about Alere's policy, and reiterated that "my physician . . . said checking [my INR level] more than once a month would not be indicated unless there is instability in my monthly checks and if this was to happen he would notify me and testing intervals would be adjusted." Id. at ¶ 26 and Exhibit O.

148. Wages responded to Allen's email within twenty-five (25) minutes, stating that "[h]ome INR testing was approved by Medicare on the basis of safety for the patients. All the studies indicate that patients who test more frequently have fewer adverse events." Id. at ¶ 27 and Exhibit O.

149. As discussed above, Wages's statement has no support in the medical literature, which at best has found a slight improvement in TTR with more frequent testing. But no high-quality study has established an improvement in clinical outcomes. Wages's reflexive response to Allen's concerns is part of an intentional effort by Alere to mislead patients (and physicians) into undergoing excessive and unnecessary INR testing solely for Alere's financial benefit.

150. Wages also informed Allen that the minimum frequency of twice per month testing was "reached by our upper management" and cannot be waived. Id. at ¶ 28 and Exhibit O.

151. On January 23, 2015, Allen emailed Wages a third time, again expressing concern that Medicare would not pay for bi-weekly testing because he had not needed it before. Id. at ¶ 29 and Exhibit P.

152. Wages responded within three (3) minutes that "Medicare will not question the frequency." Id.

153. As documented above, Allen informed Alere on no fewer than four (4) separate occasions, in writing each time, that his treating cardiologist confirmed that it was necessary that he test his INR only once monthly when his levels were stable. Despite this clear and repeated evidence that imposing a bi-weekly testing requirement on Allen would result in the performance of tests that were unreasonable and unnecessary, Alere nevertheless enrolled Allen in its home-testing program and submitted the bills for these unnecessary tests to Medicare for reimbursement.

154. Contrary to Wages's assertions, Medicare would question the frequency if it was aware that bills for unnecessary tests for stable patients were being submitted for reimbursement. Allen contacted Charles E. Haley, M.D., M.S., F.A.C.P., the Medical Director of Noridian, the Medicare Administrative Contractor ("MAC") for the region (Jurisdiction E) from which Alere submits its claims for reimbursement to CMS, to inquire about the accuracy of Wages's claims. *See* Allen Affidavit, ¶ 32 and Exhibit R.

155. Dr. Haley informed Allen that it is Noridian's position that "[o]nce a patient's INR has become stable, testing more often than monthly is rarely necessary, so would not be covered by Medicare." Id. at ¶ 32 and Exhibit S.

156. Alere enrolled Allen into its home monitoring program and has submitted bills to CMS for his INR monitoring at least once every two (2) weeks since March 11, 2015.

157. Allen has not had an INR test result that was outside of the prescribed therapeutic range since August 20, 2015. *See* Exhibit 10. In other words, Alere is aware that Allen's INR levels have been stable such that his physician would order testing to be performed once monthly if he was able to do so, but it nevertheless requires Allen to test his INR every two (2) weeks so that it can maximize its profits at the expense of Medicare.

158. As documented by the email exchange between Allen and Wages, Alere knew at the time that Allen enrolled in its program that forcing him to test more than once monthly when his INR test results were stable was medically unnecessary and contrary to the medical opinion of Allen's treating cardiologist, Dr. Riegel.

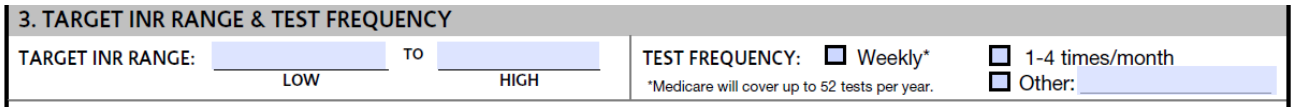
159. Allen was enrolled into the Alere program using a physician order form that indicates that it was copyrighted in 2013. This form gives prescribing physicians two (2) options: "Weekly – Medicare will cover up to 52 tests per year" or "2-4 Times Per Month – To remain on service with Alere, patients must test and report a minimum of two times each month." *See* Allen Affidavit, Exhibit Q.

160. As this was the option that required the fewest number of medically unnecessary tests, and because he had no other viable monitoring option due to the far distance of his home in relation to the nearest testing facility, Allen's physician, Dr. Riegel, agreed to sign the physician order form on January 30, 2015. *See* Exhibit 2, ¶ 22.

161. Through his investigation into Alere, Allen discovered that Alere formerly used a form called "Home INR Monitoring Physician Form," which was created in January 2011. *See* Allen Affidavit, ¶ 35, Exhibit U. This form gives prescribing physicians the options of "Weekly," "1-4 times/month," and "Other." Id. The 2011 version of the Alere enrollment form would perfectly align with testing pursuant to Dr. Riegel's prescription for Allen, which is every four (4) weeks when Allen's INR is stable. *See* Exhibit 3. The difference between the forms is illustrated below:

a. 2013 Version of Alere's Form:

b. 2011 Version of Alere's Form:



162. This change of enrollment forms was made solely to increase the amount of claims for testing supplies that Alere could submit to CMS for reimbursement by forcing physicians to order and patients to undergo medically unnecessary testing.

163. Alere's marketing practices are also intended to present warfarin patients and their physicians with misleading information to cause them to order and undergo testing at excessive frequencies. In addition to the citation to studies (and lack thereof) discussed above, Alere commissioned a retrospective analysis of data in its possession regarding patients who used its self-testing monitors from January 2008 to June 2011. It calls the evaluation of this data the Self-Testing Analysis Based on Long-term Evaluation ("STABLE").

164. The STABLE data analysis illustrates the lengths to which the defendants have gone in order to mislead and pressure physicians into ordering INR testing to be performed more frequently than they otherwise would, and more frequently than the independent scientific literature finds necessary. Grace DeSantis et al., *STABLE Results: Warfarin Home Monitoring Achieves Excellent INR Control*, 20(3) AM J MANAG CARE 202-209 (2014).

165. Alere was the sole funding source of STABLE, and seven (7) of the eight (8) authors of the study were Alere employees (the eighth was a paid consultant of Alere). Id. at 209.

166. The start date of the data analysis is inexplicably three months before CMS issued the updated NCD 190.11 coverage determination approving reimbursement of home INR monitoring for patients with atrial fibrillation. Id. at 202. Even if a large number of atrial fibrillation patients immediately transferred to home INR monitoring, which historical CMS payment data suggests was not the case, because of the arbitrary start date of the data analysis the patient population examined by STABLE is improperly skewed toward patients on warfarin treatment because of mechanical heart valves. Among other differences, patients on warfarin due to mechanical heart valves generally have a different target INR range than those with atrial fibrillation (and other underlying conditions). *See Reexamining the Recommended Follow-up Interval After Obtaining an In-Range International Normalized Ratio Value,* 140 CHEST at 360.

167. STABLE also analyzed the surrogate end point of TTR rather than the more relevant clinical benefit to patients (i.e., prevention of stroke, hemorrhage, or death).

168. The groups of patients whose data were analyzed by STABLE were also unbalanced to such a degree – 24,907 patients were in the "longer interval" group, while only 4,870 were in the weekly or bi-weekly groups – that the statistical significance of the results is highly questionable. Id. at 205.

169. Interestingly, the most useful data point from the STABLE study may be the view that it provides of the INR testing population prior to Alere's imposition of mandatory bi-weekly (or weekly) testing. The composition of the study population listed above reveals that only 15% of the patients who were using Alere's home-monitoring INR service from January 1, 2008 to June 30, 2011 were testing at the frequency that the company now mandates. The remaining 85% tested their INR at various frequencies, presumably in accordance with the direction of their physicians.

170. Alere's testing frequency mandate and marketing practices work together to mislead patients on warfarin into undergoing tests that are not medically necessary, and for which Alere submits bills to CMS for reimbursement.

171. The success of Alere's policy change is quantified by a comparison between the patients analyzed in the STABLE study (which included over 80% of Alere's home-testing patients from January 1, 2008 to June 30, 2011) and the bills Alere submitted for reimbursement by Medicare in 2015. *STABLE Results*, 20(3) AM J MANAG CARE at 205. The 29,457 patients analyzed by STABLE performed a total of 1,237,755 INR tests over a forty-two-month period, which is an average of almost exactly one INR test per month. Id. In 2015, Alere submitted billing to CMS for 1,961,268 tests (490,317 bills, with each representing four tests per the definition of HCPCS code G0249) taken by 69,142 Medicare beneficiaries, for an average of 2.36 tests per month per beneficiary. *See* Exhibit 1. Alere's scheme to remove decision-making power regarding INR test frequency from cardiologists worked exactly as it intended: it more than doubled the average number of INR tests that each patient undergoes every month.

2. Roche Health Solutions, Inc.

172. As documented above, Allen enrolled in Roche's home INR testing service in 2013 and conducted his first INR test through the program on March 2, 2014. On April 28, 2014, Roche sent Allen correspondence stating that he had failed to test for the week of April 14, 2014, despite the BCPA Coumadin Clinic (pursuant to the prescription of Dr. Riegel) directing him on April 3, 2014, to not conduct his next INR test until May 1, 2014. *See* Allen Affidavit, ¶ 12.

173. Allen was aware, based on his lengthy experience with INR testing and using the BCPA algorithm, and based on the explicit instruction provided to him by Dr. Riegel and the BCPA Coumadin Clinic, that he was to perform his next INR test in four (4) weeks. Id.

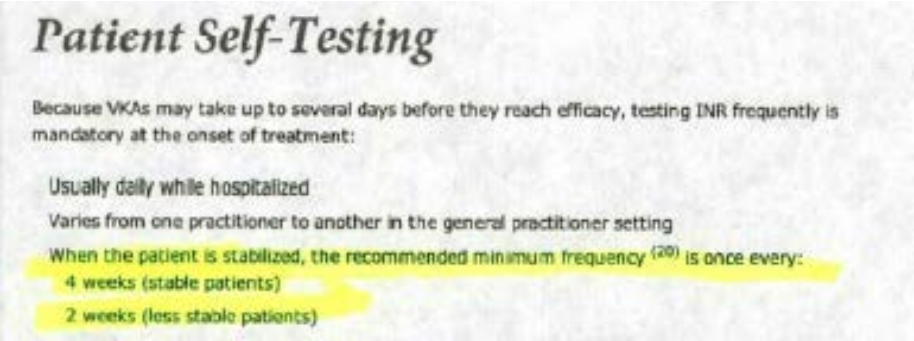
174. Allen called Roche in an attempt to uncover the source of the misunderstanding and spoke to a representative named Alisha Wittkamper ("Wittkamper"). Id. Allen was informed by Wittkamper that a "marketing report" had been circulated within Roche that directed employees to tell all patients using the Roche CoaguChek home monitors that they would be required to test their INR levels at least twice per month if they wished to continue in the Roche program. Id.

175. Allen attempted to obtain a copy of the Roche "marketing report" and was eventually referred to Roche's Director of Operations, Kirk Schaffer ("Schaffer"). Id. Schaffer informed Allen that the marketing report was for internal use only. Id. at ¶ 12 and Exhibit B.

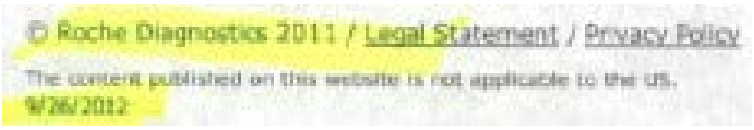
176. Despite being unable to obtain Roche's internal "marketing report" that directed that patients would be required to test their INR twice every month, Allen was able to find several Roche marketing materials published before this policy change was made that document that, like Alere, Roche formerly accommodated testing at frequencies determined by treating physicians, such as the intervals that Dr. Riegel believes to be medically necessary for Allen (namely, one time per month).

177. Allen discovered a newsletter called "At Home with CoaguChek Patient Services" that Roche circulated in June 2012 to its home-testing patients. Id. at ¶ 18 and Exhibit I. As evidenced by this newsletter, in June 2012, Roche was aware that "[s]ome people who take warfarin test their PT/INR every other week, while some test it only once a month . . . because there's no one-size fits-all testing schedule that's ideal for all patients." Id.

178. Allen also discovered that certain material on Roche's webpage was inconsistent with the information that he was receiving from Wittkamper and Schaffer, as it provided that "[w]hen the patient is stabilized, the recommended minimum frequency is once every 4 weeks (stable patients)." Id. at ¶ 19 and Exhibit J. The following is a screenshot from Roche's former website:



179. In an apparent effort to reconcile its website with the mandate it was imposing upon patients in the United States (due to the unique opportunity afforded by the CMS coverage determination allowing testing to be performed up to 52 times per year), Roche's website contained the following disclaimer: "The content published on this website is not applicable in the US. 9/26/12." Id. The disclaimer is documented below in a screenshot of Roche's website:



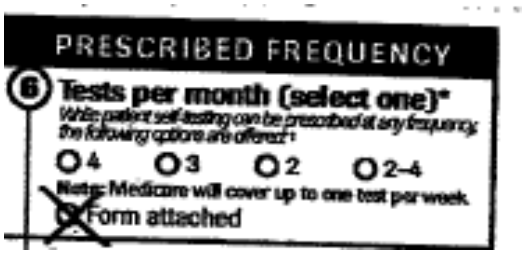
180. The difference between patients in the US and elsewhere in the world is the ease with which Roche can obtain reimbursement from Medicare for tests that are medically unnecessary.

181. Allen also discovered during his communications with Wittkamper and Schaffer that the physician enrollment form that Dr. Riegel filled out on May 8, 2013 selected a "2-4 Tests per month" option. Id. at ¶ 13 and Exhibit C.

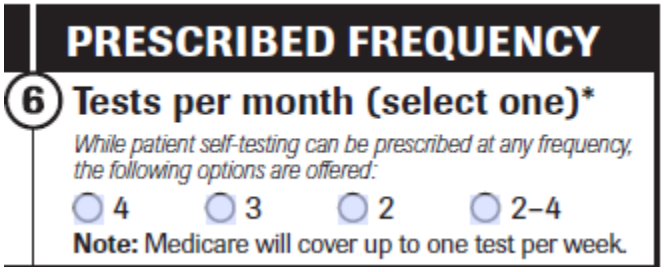
182. Allen presented his concerns to Dr. Riegel, who asked Dr. George Matthews, M.D., the Director of the BCPA Coumadin Clinic, to write a prescription clarifying that Allen was to test only once per month while his levels are stable. *See* Exhibit 2, ¶¶ 14-15; Allen Affidavit, ¶ 14 and Exhibit D.

183. Dr. Riegel countersigned the prescription and submitted it to Roche with a new enrollment form dated July 29, 2014, which selected the "Form attached" option for test frequency. *See* Allen Affidavit, ¶ 15 and Exhibits E and F.

184. Shortly after receiving this new enrollment form from Dr. Riegel, Roche updated its form to eliminate the "Form attached" option. Id. at ¶ 17 and Exhibit H. The change instituted by Roche is illustrated by the July 29, 2014 Roche enrollment form below:



When compared to the 2014 change to Roche's enrollment form after Dr. Riegel's attempt to attach a once-monthly testing prescription using the "Form attached" option:



185. In other words, after Dr. Riegel's attempt to assert his role as Allen's medical decision-maker, Roche immediately changed its enrollment form to eliminate that possibility from occurring again.

186. On August 6, 2014, Roche sent a letter to Allen, signed by Schaffer, informing that he would be dropped from Roche's home INR testing program because of the opinions of Drs. Riegel and Matthews that it was only appropriate for him to test his INR levels once monthly when stable. Id. at ¶ 16 and Exhibit G.

187. According to the records of the BCPA Coumadin Clinic, on June 30, 2014, a representative of Roche called to discuss Allen's concerns about Roche's insistence on testing in excess of Dr. Riegel's medical opinion. The Coumadin Clinic notes from that date report that nurse Susan Micholas spoke to the Roche representative and informed that the clinic does not agree with the need to test every two weeks, and that it was her belief that the only thing that could be done to address the matter was to let Allen test per BCPA's algorithm.

188. Despite the clear statements from Dr. Riegel and the BCPA Coumadin Clinic that requiring Allen to test his INR every two (2) weeks was unnecessary, Roche continued to try to force him to do so, including sending a letter the same date that the call was placed to the BCPA Coumadin Clinic (June 30, 2014) and again on July 28, 2014 warning Allen of allegedly missing test dates.

3. US Healthcare Supply

189. On January 9, 2015, Allen sent a letter to CoaguSense, Inc., in which he inquired about a home INR testing program and stated: "I have been testing once per month as prescribed by my physician as a stable patient. Can you cover that prescription for me . . . ?" Id. at ¶ 36 and Exhibit V.

190. Doug Patterson, the CEO of CoaguSense, Inc., responded to Allen by email on January 12, 2015, and suggested that Allen "can receive a Coag-Sense system at little to no cost by enrolling in a Medicare covered testing service provided by US Healthcare Supply." Id. at ¶

37 and Exhibit W. Patterson copied Kathryn Famularo ("Famularo") of US Healthcare on his email response. Id.

191. Allen followed Patterson's direction and sent an email to Famularo on January 13, 2015, in which he again stated: "I have been testing once a month as prescribed by my physician as a stable patient. Can you cover that prescription for me . . . ?" Id. at ¶ 38 and Exhibit X.

192. Famularo responded within fifteen (15) minutes, assuring Allen that Medicare "usually approves $130 a month for testing." Id. at ¶ 39 and Exhibit Y. Famularo also informed Allen that "[w]e typically don't accept monthly testers as the price of the meter is very costly and since we don't bill you or your insurance for it we require weekly or bi-weekly testing, at least for the first few months. After that, if your doctor wants you to test monthly we will respect that." Id.

193. Allen responded to Famularo by email later that same day, informing her a second time that "[m]y physician has told me that . . . checking more than once per month would not be indicated unless there is instability in my monthly checks." Id. at ¶ 40 and Exhibit Z. Allen also asked how many months he would be forced to test weekly before US Healthcare recovered the cost of the meter. Id.

194. Famularo replied eighteen (18) minutes later. Id. at ¶ 41 and Exhibit AA. She first congratulated Allen for being stable enough for monthly testing, evidencing her knowledge that she was attempting to convince Allen to undergo improper and medically unnecessary tests solely for the financial benefit of her company. Id. Famularo continued, "the meter is $700 so about 5 months to pay off the cost of the meter." Id. However, "[i]f the dr signs off on weekly testing and you test that way 4 weeks in a row and then your doctor sends in an order for monthly testing we won't dispute it . . . there are loopholes and ways around things." Id.

195. In other words, Famularo was told by Allen twice, in no uncertain terms, that it was only medically necessary that he test his INR levels once monthly. Famularo explicitly acknowledged this and told Allen that he "should be very proud" of his INR stability. She then nevertheless told him that he would have to submit to unnecessary (i.e., fraudulent) INR testing in order to become a patient of US Healthcare.

196. On January 18, 2015, Allen informed Famularo that he had spoken with his cardiologist about the information that she provided, and that his cardiologist said "4 testings per month is not medically necessary and therefore it is out of the question." Id. at ¶ 42 and Exhibit BB. He also offered to pay the $700.00 cash for the meter. Id.

197. Famularo responded the following day that "any cardiologist is able to sign off on the order." Id. at ¶ 42 and Exhibit CC. Rather than permit Allen to test at the frequency prescribed by his physician, and thus delay profiting from Medicare by several months, Famularo told Allen that "unless you get a new Cardiologist [sic] who is willing to sign off on it there is nothing we can do." Id.

4. Patient Home Monitoring, Inc.

198. In December 2014, Allen contacted PHM to inquire about enrollment into its INR home-testing program. After initially being provided with a brochure from the company, Allen sent a letter on December 29, 2014 asking: "I have been testing once to twice each month and you [sic] brochure speaks of testing 'each week.' Do I have to test 'each week' and get a new prescription or can I continue with my current schedule of testing once to twice each month? According to my doctor I am a 'stable' patient." Id. at ¶ 44 and Exhibit DD.

199. PHM representative Lisa Taguchi ("Taguchi") responded to Allen's inquiry letter by email on January 6, 2015, with a bold lie. Taguchi told Allen "since Medicare covers 80% of

the cost *they require our patients to test weekly as a preventative*. Unfortunately every other week will not work. I am aware that you are a stable patient, however for our service every week testing is a must." Id. at ¶ 45 and Exhibit EE (emphasis added).

200. PHM bills Medicare from an address in San Francisco, and therefore Noridian is the regional contractor that processes its bills. As stated above, Noridian's Medical Director, Dr. Haley, has expressly confirmed that Taguchi's statement is not only not Medicare's position, it also overstates the amount of tests that Medicare believes to be necessary for stable patients by 400%. Id. at Exhibit S.

201. Allen replied to Taguchi on January 7, 2015, pointing out that she was mistaken about the CMS coverage determination, which allows reimbursement for a maximum of one test per week, but does not have a minimum testing requirement. Id. at ¶ 46 and Exhibit FF.

202. Taguchi responded on January 12, 2015, without addressing Allen's Medicare reimbursement concern at all. She simply stated that "in order to come on board with our company, we require all of our patients to test weekly. If you would only like to test once a month unfortunately we do not allow that due to our company policy and protocol." Id. at ¶ 47 and Exhibit GG.

203. Allen independently investigated PHM's business practices, and discovered a PowerPoint presentation from April 2010, shortly after the company was founded, that explicitly described its targeting of Medicare:

> The FDA estimates at least **4 million** people in the US are currently taking blood thinners for chronic disease . . . In 2009, Medicare, the leading insurer for these patients **approved payment** to include in-home patient self-testing. **Because of this expansion of Medicare coverage, the market could reach billons and is currently growing at a massive rate**.

Id. at ¶ 48 and Exhibit HH, p. 5 (emphasis original).

204. PHM further explained to its investors how it intended to penetrate the billion-plus dollar Medicare reimbursement market it discovered: "Currently, only Roche, Philips and Inverness offer PT/INR in-home testing services. All have "pharmaceutical style marketing . . . [that] focus solely on a "health benefit" sale, promoting better patient outcomes, NOT business systemization." Id. at ¶ 49 and Exhibit HH, p. 9 (capitalization original).

205. PHM's "business systemization" marketing plan involves cutting practitioners in on the Medicare reimbursement gold mine that it believes it located: "A cardiology group can add $250,000 revenue in the first year of enrollment of 1000 patients into in-home testing." Id. at Exhibit HH, p. 10.

206. PHM's plan is nothing more than offering doctors financial inducement to write prescriptions for medically unnecessary testing.

207. The disregard for patient "health benefit" in favor of maximizing Medicare reimbursement is also evident on PHM's "Self-Testing Referral Form." The patient's warfarin history and ICD-9/10 diagnosis codes track the CMS coverage determination, to ensure that patients who are not Medicare-eligible are not enrolled. The form then says that "[p]atient self-testing is a service that requires the patient or the patient's caregiver to administer a PT/INR test and report the results on a weekly basis to [PHM] for the duration of the patient's anticoagulation therapy." Despite this weekly obligation for the patient (because the patient action of conducting the test is the necessary act for PHM to submit reimbursement), it allows the physician to elect to receive only "Monthly summaries" of the test results. This means that even as PHM is requiring patients to test their INR once per week, the weekly tests are not actually being used to evaluate and adjust their warfarin dosage if the physician selects the "Monthly summaries" option. *See* Exhibit 5.

5. Advanced Cardio Services

208. Allen contacted ACS in December 2014 to inquire about its INR home-testing program. *See* Allen Affidavit, ¶ 52.

209. ACS's Operations Coordinator, Kayla Lang, responded on December 5, 2014 by forwarding ACS's promotional materials. Id. at ¶ 53 and Exhibit JJ.

210. The materials forwarded to Allen by ACS also included its "Physician Order/Prescription for PT/INR Patient Self-Testing." Id. at ¶¶ 53-54 and Exhibit JJ.

211. The certifications required by the form pertaining to the patients' warfarin history and ICD-9/10 diagnosis codes track the CMS coverage determination, to ensure that patients who are not eligible for Medicare reimbursement are not enrolled. This form also states in four separate places that ACS requires patients to test weekly. However, ACS allows doctors to select a test result reporting option of "Only Out of Range Results + Monthly Summary Report." In other words, despite requiring patients to undergo medically unnecessary tests, ACS does not ensure that the test results are actually used to monitor and influence the patient's warfarin dosage, as physicians can elect to only review the test results monthly. Id.

212. More egregiously, the ACS enrollment form also prominently states that "Medicare recommends weekly testing," as illustrated below:

Id.

213. ACS uses a billing address in Carlsbad, California to submit bills to Medicare for reimbursement, and therefore Noridian is the regional contractor that processes its submissions.

As stated above, Noridian's Medical Director, Dr. Haley, has expressly confirmed that ACS's statement is a lie intended only to mislead patients into medically unnecessary INR testing. Id. at Exhibit S. As Dr. Haley explained, not only does Medicare not "recommend" weekly INR testing, it is Medicare's position that testing more than monthly is "rarely necessary" for stable patients. Id.

214. Allen sent a letter to ACS on January 7, 2015. This letter again inquired about the company's home INR testing service, and specifically asked if it would be able to cover Allen's prescription for testing once per month when stable. Id. at ¶ 55 and Exhibit KK.

215. On January 13, 2015, Linda Aano ("Aano"), ACS's New Patient Coordinator, told Allen that "Medicare has recently determined that weekly testing reduces complications associated with Coumadin therapy so they cover the majority of the cost of ACS' INR home monitoring services." Id. at ¶ 56 and Exhibit LL.

216. Aano also forwarded another ACS flyer with her January 13, 2015 email that states that "Medicare has determined that weekly home testing compared to traditional monthly lab tests can lead to fewer complications associated with Coumadin therapy." Id.

217. These statements made by Aano, the ACS enrollment form, and the marketing materials that were sent to Allen are each intentional lies, made to take advantage of a sick and vulnerable population so that ACS can increase its profit.

218. When Allen asked for a copy of the "Medicare determination" that Aano was referring to, she responded with the CMS Decision Memorandum explaining the issuance of the 2008 update to NCD 190.11 and a copy of Alere's STABLE data analysis. Id. at ¶ 57 and Exhibits MM and NN. Neither of these documents contains reference to any determination by Medicare that weekly INR testing improves patient outcomes.

219. Having received no response to her inadequate explanation from Allen, on January 23, 2015, Aano again emailed Allen to ask if he would be signing up for ACS's home INR testing services. Id. at ¶ 58 and Exhibit OO.

220. On January 24, 2015, Allen responded that he is hesitant to do so, because he knows that Medicare requires testing to be medically necessary and he has "been told once a month testing for me is correct and to use my [Medicare] benefits when I don't need them could create a problem." Id. at ¶ 58 and Exhibit PP.

221. Following this clear statement that it is only medically necessary for him to perform INR tests once monthly, Allen asked "[h]as Medicare stated that it is ok to use the extra additional tests as long as you do not exceed the weekly testing?" Id.

222. Aano responded with one sentence: "Yes, Medicare covers our services." Id. at ¶ 58 and Exhibit QQ.

223. This response is again an intentional misrepresentation of Medicare's reimbursement policies that informed a potential patient that it was perfectly acceptable to undergo medically unnecessary testing for ACS's financial benefit.

6. mdINR, LLC

224. Allen contacted mdINR to inquire about its INR home-testing program on January 7, 2015 and followed an initial telephone conversation with a letter asking about Medicare coverage and inquiring as to whether mdINR would cover a prescription that would allow him to test either once or twice per month, as directed by his physician. Id. at ¶ 60 and Exhibit RR.

225. He received a response via email from Inside Sales Rep Theresa Hoff-Cimilluca ("Hoff-Cimilluca") on January 13, 2015. Despite Allen's clear statement regarding the

frequency that his physician believed to be medically necessary for him to test, Hoff-Cimilluca stated "you should be 100% covered for our service [by Medicare]. We are weekly only testing, so you and your doctor must agree to weekly testing to use our service." Id. at ¶ 61 and Exhibit SS.

226. Hoff-Cimilluca's response to Allen's inquiry makes clear at the outset that mdINR would rather pressure patients and physicians into ordering medically unnecessary tests than permit testing to be performed pursuant to a medical decision-making process.

227. Hoff-Cimilluca also forwarded mdINR's "Physician Order Form." As with other IDTFs, the order form requires the physician to sign off on a statement that the patient has been on warfarin for over 90 days and that the patient's diagnosis is among those that are included in the governing CMS coverage determination, so as to filter out those patients for whom mdINR may not be able to obtain Medicare reimbursement. The pre-printed physician statement also says "[i]t is medically necessary for this patient to test his/her INR values frequently to stabilize coagulation and avoid negative outcomes." Notwithstanding this apparent concern for getting physician's weekly data points to stabilize coagulation, mdINR permits physicians to select a reporting option of "Only Fax Out of Range Results." It is possible that the options that mdINR's order form gives to prescribing physicians could result in a patient testing his/her INR every single week, but without a doctor ever seeing the results. Id. at ¶ 62 and Exhibit TT.

228. Allen discovered that the representations made by Hoff-Cimilluca and the mdINR enrollment form were inconsistent with mdINR's own marketing materials. mdINR's website contains a step-by-step description of the home INR testing process, which includes: "Step 1: **Test yourself at home at the frequency prescribed by your doctor**, usually weekly." Id. at ¶ 63 and Exhibit UU (emphasis added). The website material is reproduced below:

Step 1:
Test yourself at home at the frequency prescribed by your doctor, usually weekly.

229. mdINR only allows doctors to prescribe weekly testing; the frequency with which patients in its program must test their INR does not change and does not take into account "the frequency prescribed by your doctor."

7. Tambra Investments, Inc. d/b/a Real Time Diagnostics

230. Allen contacted RTD by telephone in November 2015 to inquire about its home INR testing service. During the initial conversation with RTD, Allen explained that his physician instructs him to perform INR testing monthly when his levels are stable. Id. at ¶ 65.

231. On November 11, 2015, Allen sent a follow-up letter to RTD asking for additional information regarding the increased TTR and reduced complications that RTD claimed its service provides, and explained that "[m]y physician has stated he believes I should continue to test once a month through your home testing program." Id. at ¶ 65 and Exhibit VV.

232. RTD's initial response was received by Allen on November 16, 2015, and included only promotional brochures. Id. at ¶ 67 and Exhibit XX.

233. Allen then made a second request for specific information to provide to his physician, which was responded to by email by Cheryl Bradley, RTD's Coumadin Care Coordinator, on November 17, 2015. Bradley listed citations to a World Health Organization study from 2003 that has nothing to do with INR testing, the CMS Decision Memorandum from the first coverage determination for home INR testing in 2001, two studies comparing warfarin to next-generation anticoagulants that have nothing to do with home monitoring frequency, and a study evaluating portable INR monitors from 1993. Id. at ¶ 68 and Exhibits YY and ZZ.

234. Allen replied to Bradley by email on November 19, 2015, pointing out that none of the publications that she referenced support the representations made by RTD about improving patient outcomes, and expressing that it was his position that RTD was mandating a testing frequency in order to increase its own profit. Allen also mailed a copy of this letter to RTD's CEO, Michael Evans. Id. at ¶ 69 and Exhibit AAA.

235. On December 1, 2015, Allen sent a second letter to Bradley and Evans in which he provided citation to the current CMS Decision Memorandum for NCD 190.11 and asked again for the justification that RTD relied upon to force patients to test their INR on a weekly basis. Id. at ¶ 70 and Exhibit BBB.

236. On December 3, 2015, RTD's Laboratory Director, Thomas Gallant, called Allen to advise that answers to his inquiries would not be forthcoming. Id. at ¶ 71.

237. Allen further investigated RTD's marketing practices and discovered that, like PHM, RTD focuses its marketing efforts on inducing physicians to use its service with promises of increased income. Id. at ¶ 66.

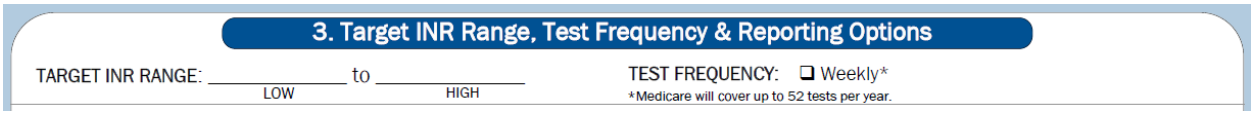
238. RTD's webpage titled "Information for Physicians" boasts "**More Revenue. More Data. Less Effort.**" Id. at Exhibit WW (emphasis original). Specifically, it claims that a medical practice will "have a new, recurring revenue source from the review and interpretation of patient self-testing results . . . [its] nursing staff will be free to focus on other patient-care tasks . . . and [it will] be able to maintain a regular patient office visit schedule – possibly increasing the number of Level 4 office visits annually." RTD represents that this will increase a practice's annual revenue per patient by $265.14. Id.

239. In other words, RTD's scheme not only increases the number of medically unnecessary INR test claims for reimbursement to Medicare, it also increases the number of claims to Medicare for reimbursement of high-level office visits.

240. RTD also makes particularly misleading statements regarding the benefits of home testing to patients. For example, RTD claims that "[c]linical studies, [sic] have shown more frequent PT/INR testing lowers the risk of serious medical complications like stroke and bleeding." Id. This statement is unattributed, but as discussed above, studies have not proven any clinical benefit to increased frequency of testing.

241. RTD provides a chart that lists studies that it claims support its assertions of a health benefit. The most recent study was published in 1996. Id. RTD continues to refer to these outdated studies because it needs to influence patients to undergo unnecessary testing so that it can obtain the maximum amount of reimbursement that Medicare permits.

242. The enrollment form used by RTD requires a physician to certify that the patient has been on warfarin for over 90 days and will undergo a training program on use of the device, both of which are prerequisites to Medicare coverage and are used on the form to ensure that patients who are not eligible for Medicare reimbursement are not enrolled. The form also states that Medicare will cover up to 52 tests per year, but makes no representations with regard to any other payor source. The form has a box to check to select the test frequency, but the only option is "Weekly." As with the other IDTFs, RTD's pre-printed enrollment form removes the ability of treating physicians to direct their patient's care on an individual basis. *See* Exhibit 7. The test frequency "options" offered by RTD are reproduced below:



8. Cardiolink Corp.

243. In November 2014, Allen contacted Cardiolink and spoke to its "Tech Division" Vice President, Richard Scheffel. *See* Allen Affidavit, ¶ 73.

244. Allen asked Scheffel if Cardiolink would honor his physician's instruction to test his INR on a monthly basis when his levels are stable. Scheffel replied that Allen can test his INR once per month if he chooses, but that Scheffel or Cardiolink will nevertheless bill Medicare for four (4) tests per month. Id., at ¶ 74.

245. Cardiolink's "Physician Prescription Form" appears to give physicians the ability to retain their medical decision-making role by allowing them to choose frequencies of "1 Test Per week" or "Other." *See* Exhibit 6.

246. However, as Allen discovered during his conversation with Scheffel, Cardiolink goes a step further than each of the other defendant IDTFs (at least explicitly), and submits the maximum number of claims for reimbursement to Medicare per patient, regardless of whether the patient actually took the test.

247. Further, Scheffel informed Allen that Cardiolink's training on the use of the self-testing device is limited to sending an instructional DVD. Id., at ¶ 75. This does not satisfy the requirement of NCD 190.11 that all patients receive "face-to-face" training before use.

VII. IMPROPER BILLING OF HCPCS CODE G0249

A. HCPCS CODE G0249 REQUIREMENTS

248. As discussed above, HCPCS code G0249 is the billing vehicle through which the defendants each submitted their fraudulent charges for medically unnecessary INR testing to CMS for reimbursement.

249. To properly bill for G0249, the defendants must meet the following criteria:

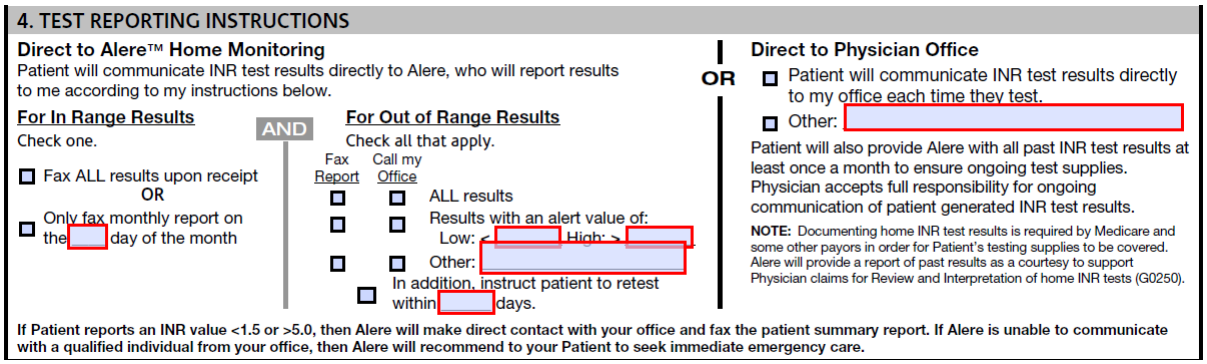
> Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes provisions of materials for use in the home and reporting of test results to physician; not occurring more frequently than once a week.

See CMS Manual Chapter 32, Section 60.4.2. As discussed above, HCPCS code G0249 by definition can only be billed once for every four (4) tests.

250. In addition to these specific requirements, the test itself must be prescribed by a treating physician as provided at 42 CFR § 410.32(a).

251. The enrollment forms used by Alere, mdINR, PHM, RTD, and ACS allow a physician to elect to receive only out-of-range results and/or only monthly summaries of INR test results. *See* Allen Affidavit, Exhibits Q, U, JJ, TT; Exhibits 5 and 7. The options are illustrated below:

a. **Alere**:



4. TEST REPORTING INSTRUCTIONS

Direct to Alere™ Home Monitoring
Patient will communicate INR test results directly to Alere, who will report results to me according to my instructions below.

For In Range Results
Check one.
☐ Fax ALL results upon receipt
OR
☐ Only fax monthly report on the ____ day of the month

AND

For Out of Range Results
Check all that apply.

Fax Report	Call my Office	
☐	☐	ALL results
☐	☐	Results with an alert value of: Low: < ____ High: > ____
☐	☐	Other: ____

☐ In addition, instruct patient to retest within ____ days.

OR

Direct to Physician Office
☐ Patient will communicate INR test results directly to my office each time they test.
☐ Other: ____

Patient will also provide Alere with all past INR test results at least once a month to ensure ongoing test supplies. Physician accepts full responsibility for ongoing communication of patient generated INR test results.

NOTE: Documenting home INR test results is required by Medicare and some other payors in order for Patient's testing supplies to be covered. Alere will provide a report of past results as a courtesy to support Physician claims for Review and Interpretation of home INR tests (G0250).

If Patient reports an INR value <1.5 or >5.0, then Alere will make direct contact with your office and fax the patient summary report. If Alere is unable to communicate with a qualified individual from your office, then Alere will recommend to your Patient to seek immediate emergency care.

b. **mdINR**:

Fax Options

☐ Fax Every Result

☐ Only Fax Out of Range Results BELOW: _____ ABOVE: _____

☐ Fax Out of Range + Monthly Summary BELOW: _____ ABOVE: _____

c. **PHM**:

Test Frequency: **Weekly**	Target INR Range: ____ (low) to ____ (high)
Reporting Preference:	☐ Weekly reports (one report for each test) ☐ Monthly summaries (first of the month)

d. **RTD**:

TEST REPORTING INSTRUCTIONS:
Patient will communicate test results directly to RTD who will report INR test results to me according to my instructions below.
If patient obtains an INR result outside of the Target Range then:
❑ RTD should contact my office immediately
❑ RTD should instruct patient to retest within _____ days
❑ Other: _____

NOTE: if patient reports an INR value <1.5 or >5.0, then RTD will *always* make direct contact with your office. If RTD is unable to communicate with a qualified individual from your office, then RTD will recommend to your patient to seek immediate emergency care.

e. **ACS**:

F. REPORTING INSTRUCTIONS

Patient will report INR test results directly to Advanced Cardio Services. **ACS will:**

☐ **Fax** Results to **Physician:** ☐ **Fax** Results to **Coumadin Clinic:** ☐ **E-Mail** Results:

Physician: (Fax#) _____

OR

Coumadin Clinic: (Fax# required) _____

OR

E-mail Address: _____

How Often:

☐ All Test Results

☐ Only Out of Range Results + Monthly Summary Report

Id.

252. The options on the enrollment forms that do not result in the "reporting of test results to physician" fail to meet the requirements to submit a bill for reimbursement of G0249.

253. Each time a defendant IDTF submitted a bill to Medicare using HCPCS code G0249 where the results of the INR tests billed were not reported to the prescribing physician, such submission amounted to billing for services that were not actually rendered. All such bills are fraudulent.

B. ALERE SUBMITTED CHARGES USING HCPCS CODE G0249 FOR FEWER THAN FOUR TESTS

254. As discussed above, HCPCS code G0249 is only properly billed after a patient performs, and the IDTF reports the results of, four (4) INR tests. Alere, however, fraudulently billed after only three (3) INR tests were performed on multiple occasions, despite the clear definition of code G0249 and despite Alere knowing that G0249 can only lawfully be billed after the performance of four (4) tests.

255. For example, on September 5, 2016, Alere submitted a claim to Medicare for one unit of HCPCS code G0249 for INR tests that were performed by Allen on July 24, 2016, August 7, 2016, August 22, 2016, and September 5, 2016. *See* Exhibit 11.

256. Alere next submitted a claim for reimbursement to Medicare for one unit of HCPCS code G0249 on October 16, 2016 relative to tests performed by Allen. *See* Exhibit 12.

257. As documented by Allen's test result history maintained by Alere, Allen only performed three (3) INR tests prior to the submission of the October 16, 2016 claim for reimbursement, namely, on September 18, 2016, October 2, 2016, and October 16, 2016. *See* Exhibit 13.

258. Alere's submission of a claim for reimbursement for a unit of HCPCS code G0249 on October 16, 2016 falsely represented that it had provided Allen with supplies to

perform four (4) INR tests, that Allen had in fact performed four (4) INR tests, and that Alere had reported four (4) INR test results to Allen's physician, all of which was false.

259. This fraudulent claim for reimbursement was not an isolated incident. On December 2, 2016, Alere again submitted a claim for a unit of HCPCS code G0249 after Allen had performed and Alere had reported the results of just three (3) INR tests, namely, on October 30, 2016, November 17, 2016, and December 2, 2016. *See* Exhibit 14.

260. Alere's practice of submitting claims for reimbursement for units of HCPCS code G0249 before patients actually perform four (4) tests results in a 33.3% increase in the amount billed to Medicare at no cost to Alere, as such bills are for services that it never actually performed.

261. Extrapolated over the entire population of patients for whom Alere provides supplies for home INR testing, this fraudulent billing practice could cost Medicare over $12,000,000 per year in claims for services that were not provided by Alere.

262. Allen's INR results were within his target range for each of the tests that were included in the improperly billed units of HCPCS G0249, meaning that the charges submitted by Alere included both medically unnecessary testing imposed by its policies (discussed *supra*) and billing for services not rendered.

C. HCPCS CODE G0249 BILLING HISTORY

263. In 2008, CMS paid a total of $5,548,306 for all bills submitted with HCPCS code G0249.

264. In 2015 (the latest year for which data is available), CMS paid a total of $128,527,467.01 for all bills submitted with HCPCS code G0249. This is an increase of approximately 2,200% in payments for bills submitted using G0249 over seven (7) years.

265. The increase is the result of the test frequency policies imposed by the defendants that require all patients to undergo frequent testing, regardless of their physicians' judgment.

266. As discussed above, Alere's STABLE analysis shows that home monitoring patients tested almost exactly one (1) time per month from January 1, 2008 to June 30, 2011. In 2015, the defendants submitted bills for INR testing at the following rates:

a. **Alere:** 2.36 tests per patient per month (1,961,268 tests taken by 69,142 patients)

b. **Roche:** 1.74 tests per patient per month (462,524 tests taken by 22,161 patients)

c. **ACS:** 2.80 tests per patient per month (57,052 tests taken by 1,698 patients)

d. **PHM:** 2.90 tests per patient per month (80,868 tests taken by 2,323 patients)

e. **US Healthcare:** 1.95 tests per patient per month (14,952 tests taken by 639 patients)

f. **mdINR:** 2.86 tests per patient per month (1,751,244 tests taken by 51,053 patients)

g. **RTD:** 2.48 tests per patient per month (112,812 tests taken by 3,793 patients)

h. **Cardiolink:** 2.85 tests per patient per month (1,436 tests taken by 42 patients)

267. Not surprisingly, the defendants that were the most militant in their insistence that the Relator test his INR weekly are the ones that submit the most average bills per patient using G0249.

268. The total average INR tests per patient per month performed in 2015 is 2.45 (4,442,156 tests taken by 150,851 patients). This is 2.45 times the rate of testing that was documented by Alere's analysis of its actual patient population before the defendants began imposing mandatory minimum testing frequencies, and it suggests that of the $128,527,467.01 paid by CMS in 2015, $76,067,276.38 was paid for tests that would not have been performed at

all (i.e., are medically unnecessary) had the defendants continued allowing prescribing physicians to determine the appropriate test intervals for their patients.

VIII. CAUSES OF ACTION

COUNT I
VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(A)
All Defendants

269. Allen re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 268 set forth above.

270. In violation of 31 U.S.C. § 3729(a)(1)(A), the defendants knowingly acted with reckless disregard or deliberate ignorance of their truth or falsity presented or caused to be presented false or fraudulent claims for payment or approval to the United States of America, including claims for INR testing services that were not medically necessary, that were fraudulently billed, or that represented reimbursements that should have been refunded as overpayments to the United States of America.

271. The United States of America directly or indirectly, including through several Medicare Administrative Contractors, made payments to the defendants based upon the false and fraudulent claims.

272. The United States of America is entitled to a full recovery of the amount paid to the defendants based on the false claims submitted or caused to be submitted by the defendants.

273. By virtue of these false or fraudulent claims on the part of the defendants, the United States of America suffered damages and therefore is entitled to treble damages under the False Claims Act, as determined at trial, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation.

COUNT II
VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(B)
All Defendants

274. Allen re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 268 set forth above.

275. The defendants knowingly or acting with reckless disregard or deliberate ignorance of their truth or falsity made, used, or caused to be made or used a false record or statement material to a false or fraudulent claim to receive a payment on false and fraudulent claims from federally funded insurance programs such as Medicare and Medicaid.

276. The United States of America directly or indirectly, including through various Medicare Administrative Contractors, made payments to the defendants based upon the false record or statements submitted by the defendants.

277. The United States of America is entitled to full recovery of the amount paid to the defendants based on the submission of false records or statements material to false or fraudulent claims.

278. By virtue of these false or fraudulent claims on the part of the defendant, the United States of America suffered damages and therefore is entitled to treble damages under the False Claims Act, as determined at trial, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation.

COUNT III
VIOLATIONS OF 31 U.S.C. § 3729(a)(1)(G)
All Defendants

279. Allen re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 268 set forth above.

280. The defendants knowingly or acting with reckless disregard or deliberate ignorance of their truth or falsity concealed or knowingly or acting with reckless disregard or deliberate ignorance improperly avoided or decreased an obligation to pay or transmit money or property to the United States of America for overpayments received from federally-funded insurance programs such as Medicare and Medicaid.

281. By virtue of these false or fraudulent claims on the part of the defendants, the United States of America suffered damages and therefore is entitled to treble damages under the False Claims Act, as determined at trial, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation.

COUNT IV
PAYMENT UNDER MISTAKE OF FACT
All Defendants

282. Allen re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 268 set forth above.

283. This is a claim for the recovery of monies paid by the United States of America to the defendants as a result of mistaken understandings of fact.

284. The false claims the defendants submitted to the United States of America were paid based upon the mistaken or erroneous understanding of material facts.

285. The United States of America, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of the defendants' certifications and representations, paid the defendants significant sums of money to which the defendants were not legally entitled and are thus liable to account for and pay such amounts, as determined at trial, to the United States of America.

COUNT V
UNJUST ENRICHMENT
All Defendants

286. Allen re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 268 set forth above.

287. This is a claim for the recovery of monies by which the defendants have been unjustly enriched.

288. By directly or indirectly obtaining federal funds to which the defendants were not legally entitled, the defendants were unjustly enriched and are liable to account and pay such amounts, as determined at trial, to the United States of America.

289. The false claims the defendants submitted to the United States of America were paid based upon the mistaken or erroneous understanding of material facts.

290. The United States of America, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of the defendants' certifications and representations, paid the defendants significant sums of money to which the defendants were not legally entitled and are thus liable to account for and pay such amounts, as determined at trial, to the United States of America.

IX. DEMAND FOR RELIEF

WHEREFORE, Relator James F. Allen and the United States of America respectfully request that judgment enter in their favor, as follows:

A) That this Court enter judgment under Counts I through III against the defendants in an amount equal to three times the amount of damages the United States of America has sustained because of the defendants' actions, plus a civil penalty of not less than $5,000 or more than $10,000 for each

false or fraudulent claim submitted in violation of 31 U.S.C. § 3729, *et seq*.;

B) That the Relator be awarded all costs incurred, reasonable attorney's fees, and expenses;

C) That in the event the United States of America intervenes at the time this action is unsealed and proceeds with this action, the Relator be awarded an amount of at least 15% but not more than 25% of the proceeds of this action or settlement of the claims;

D) That in the event the United States of America does not intervene as set forth above, the Relator be awarded an amount of at least 25% but no more than 30% of the proceeds of this action or settlement of the claims; and

E) That the Relator and the United States of America receive all relief, both at law and equity, to which they are entitled.

X. JURY TRIAL DEMAND

The Relator hereby demands a trial by jury on all claims.

[SIGNATURE PAGE FOLLOWS]

Respectfully Submitted,

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Dated: June 29, 2017

CERTIFICATE OF SERVICE

I, Jacquelyn A. McEttrick, hereby certify that on June 29, 2017, I served the foregoing document and all exhibits thereto via electronic mail pursuant to agreement of the parties to the following:

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